SEP 1 9 2001

K012079

510(k) SUMMARY

Submitter's name: Electrical Geodesics, Inc.
1850 Millrace Drive
Eugene, OR 97403
541-687-7962

Date summary prepared: June 25, 2001

Device name:

Proprietary name: Geodesic EEG System™
Common or usual name: EEG machine
Classification name: Electroencephalograph, 84 GWQ
Class II, 21 CFR 882.1400.

The product includes the Geodesic Sensor Net® which has the following identifiers:

Common name: EEG electrode
Classification name: Cutaneous electrode, 84 GXY
Class II, 21 CFR 882.1320.

Legally marketed device for substantial equivalence comparison:

For the Geodesic EEG System it is the Bio-Logic Ceegraph 128-Channel Recording System submitted by Bio-Logic Systems Corporation and cleared for marketing under 510(k) #K973883. For the Geodesic Sensor Net, the predicate device is the Electro-Cap VII System submitted by Electro-Cap Inc. and cleared for marketing under 510(k) #K780045.

Description of the device:

The Geodesic EEG System is a digital electroencephalography system (EEG) with a dense sensor array of 32 to 256 channels. Like existing digital EEG systems, the Geodesic EEG System is computer controlled and capable of acquiring, storing, and displaying data. It includes scalp conductive electrodes, amplifiers, a central processing unit, and software. The Geodesic Sensor Net is a dense array of scalp electrodes designed to allow rapid application in an even distribution across the head. The Net Amps™ consists of multiple amplifiers for physiological signals that are fully software controlled. Net Station® is the software package that provides control of the Geodesic EEG System, digital data storage, and operator-selected waveform displays. The software does not perform any data analysis. Additional components of the system are an articulated arm with extended cable, rack system, various cables, standard components of personal computer (monitor, keyboard, mouse), electrolyte solution, and disinfectant.

The Geodesic EEG System is a new device that has not previously been submitted to FDA. It has features similar to other digital EEG devices on the market.

Intended use of device:

The Geodesic EEG System is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

Technological characteristics:

The technological characteristics of the Geodesic EEG System are similar to those of other digital EEG systems, including the predicate device, the Ceegraph 128-Channel Recording System. Each product is an EEG machine that is software controlled, can accommodate a variable number of electrodes, and can acquire, display, and record EEG data. Some differences in electrical parameters are described. Differences in the software include that the products use different operating systems and that Net Station does not analyze the data. Another difference is that the Geodesic EEG System has dedicated electrodes, the Geodesic Sensor Net.

The Geodesic Sensor Net is compared to the Electro-Cap VII System. Each product consists of a structure that links a number of electrodes so that they can be easily applied to the patient. The Geodesic Sensor Net uses a geodesic array of electrodes with equal distribution across the head. The Electro-Cap uses the 10-20 array. The Geodesic Sensor Net can accommodate a larger number of electrodes. Finally, the Geodesic Sensor Net does not require scalp abrasion for use.

Testing conducted:

Testing was conducted to ensure compliance with international standards related to electroencephalographs. The general safety standards used were: CAN/CSA C22.2 No. 601.1-M90 including Supplement 1 and Amendment 2 and UL Std. No. 2601-1 (2nd Edition). The electromagnetic compatibility standard was EN60601-1-2(1993). The electroencephalograph standards were IEC 60601-2-26 and CAN/CSA C22.2 No. 601.2.26. The biocompatibility standard was ISO 10993. The Geodesic EEG System passed all testing.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Electrical Geodesics, Inc.
c/o Mr. Robert S. McQuate
R. S. McQuate & Associates, Inc.
3636 E. Columbine Drive
Phoenix, Arizona 85032

Re: K012079
Trade/Device Name: Geodesic EEG System™
Regulation Number: 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: June 29, 2001
Received: July 3, 2001

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, M.D.

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K012079

Device name: Geodesic EEG System™

Indications for Use:

The Geodesic EEG System is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

K012079

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012079